

**Preliminary Amendment**  
**U.S. Patent Application No. 10/544,248**

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1. (Currently Amended) Pharmaceutical composition, characterised in that it contains one or more anticholinergics (1) A pharmaceutical composition comprising at least one anticholinergic in combination with one or more Inhibitors at least one inhibitor of TNF alpha synthesis or action, (2) wherein the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action are optionally in the form of the individual optical isomers, mixtures thereof or racemates thereof, and are optionally in the form of the pharmacologically acceptable acid addition salts thereof, and are optionally in the form of the solvates or hydrates and optionally together with a pharmaceutically acceptable excipient.

2. (Currently Amended) Pharmaceutical The pharmaceutical composition according to claim 1, characterised in that 1 wherein the at least one anticholinergic is selected from among the group consisting of tiotropium salts, oxitropium salts [[or]] and ipratropium salts, preferably tiotropium salts.

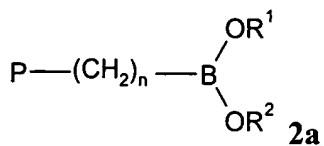
3. (Currently Amended) Pharmaceutical The pharmaceutical composition according to claim 2, characterised in that 1 wherein the at least one anticholinergic is present in the form of the comprises at least one of a chloride, a bromide, an iodide, a methanesulphonate [[or]] and a para-toluenesulphonate, preferably in the form of the bromide.

4. (Currently Amended) Pharmaceutical The pharmaceutical composition according to one of claims 1 to 3 claim 1, characterised in that 2 wherein the at least one inhibitor of TNF alpha synthesis or action is at least one of GENZ 80825, GENZ 34940, GENZ 29155, [[or]] and RDP-58.

5. (Currently Amended) Pharmaceutical The pharmaceutical composition according to claim 4, characterised in that 2 wherein the at least one inhibitor of TNF alpha synthesis or action is RDP-58.

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6. (Currently Amended) Pharmaceutical The pharmaceutical composition according to one of claims 1 to 3 claim 1, characterised in that 2 wherein the at least one inhibitor of TNF alpha synthesis or action is selected from the compounds comprises a compound of formula 2a:



wherein:

R<sup>1</sup> and R<sup>2</sup> are both hydrogen atoms, or together are a propylene chain bridging the two oxygen atoms;

n is 2-6; and

P is a purine, indole or pyrimidine base residue bonded via the N<sup>9</sup> in the case of purine base or via the N<sup>1</sup> in the case of an indole or pyrimidine base, and the pharmaceutically acceptable salts thereof.

7. (Currently Amended) Pharmaceutical The pharmaceutical composition according to one of claims 1 to 6 claim 1, characterised in that the active substances 1 and 2 wherein the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action are present either together in a single formulation or in two separate formulations.

8. (Currently Amended) Pharmaceutical The pharmaceutical composition according to one of claims 1 to 7 claim 1, characterised in that wherein the weight ratio[[s]] of 1 to 2 are the at least one anticholinergic to the at least one inhibitor of TNF alpha synthesis or action is in the range from 1:1000 to 1:1, preferably from 1:250 to 1:2.

9. (Currently Amended) Pharmaceutical The pharmaceutical composition according to one of claims 1 to 8 claim 1, characterised in that wherein the pharmaceutical composition is provided in a single administration amount corresponds to including a dose of the active substance combination 1 and 2 of the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action in an amount of 1  $\mu$ g to 10000  $\mu$ g, preferably from 10 to 5000  $\mu$ g.

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10. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~one of claims 1 to 9~~ claim 1, ~~characterised in that it~~ wherein the formulation is in the form of a formulation suitable for inhalation.

11. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 10, ~~characterised in that it~~ wherein the formulation is a formulation selected from ~~among the group consisting of~~ inhalable powders, propellant-containing metering aerosols and propellant-free inhalable solutions or suspensions.

12. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 11, ~~characterised in that it~~ wherein the formulation is an inhalable powder which ~~contains 1 and 2~~ includes the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action in admixture with ~~at least one~~ suitable physiologically acceptable excipient[[s]] selected from ~~among the group consisting of~~ monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, [[or]] and mixtures ~~thereof~~ of these excipients ~~with one another~~.

13. (Currently Amended) ~~Inhalable~~ An inhalable powder ~~comprising the pharmaceutical composition~~ according to claim 12, ~~characterised in that the~~ wherein the at least one excipient has a maximum average particle size of up to 250 µm, preferably between 10 and 150 µm.

14. (Currently Amended) ~~Capsules,~~ characterised in that they contain A capsule containing an inhalable powder according to claim 12 or 13.

15. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 11, ~~characterised in that it~~ wherein the pharmaceutical composition is an inhalable powder ~~which contains only the active substances 1 and 2 as its ingredients~~ consisting of the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action.

16. (Currently Amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 11, ~~characterised in that it~~ wherein the pharmaceutical composition is a

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propellant-containing inhalable aerosol which ~~contains 1 and 2~~ includes the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action in dissolved or dispersed form.

17. (Currently Amended) Propellant-containing inhalable aerosol ~~The pharmaceutical composition according to claim 16, characterised in that it contains wherein the propellant-containing inhalable aerosol includes~~, as propellant gas, ~~at least one of hydrocarbons such as n-propane, n-butane, [[or]] isobutene, or halohydrocarbons such as chlorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane, and[[/or]] fluorinated derivatives of methane, ethane, propane, butane, cyclopropane or cyclobutane.~~

18. (Currently Amended) Propellant-containing inhalable aerosol ~~The pharmaceutical composition according to claim 17, characterised in that wherein~~ the propellant gas is TG134a, TG227, or a mixture thereof.

19. (Currently Amended) Pharmaceutical ~~The pharmaceutical~~ composition according to claim 11, ~~characterised in that it wherein the pharmaceutical composition~~ is a propellant-free inhalable solution or suspension ~~which contains including~~ water, ethanol or a mixture of water and ethanol as solvent.

20. (Currently Amended) Inhalable solution or suspension ~~The pharmaceutical composition according to claim 19, characterised in that it wherein the pH [[is]] of the inhalable solution or suspension ranges from 2-7, preferably 2-5.~~

21. (Currently Amended) Use of a capsule according to claim 14 in an inhaler, preferably in a Handihaler. ~~A method of providing a dosage of an inhalable powder comprising: providing a capsule containing an inhalable powder according to claim 14; and administering a dosage of the inhalable powder in the capsule using an inhaler.~~

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22. (Currently Amended) ~~Use of an inhalable solution according to one of claims 19 or 20 for nebulising in an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687. A method of providing a dosage of an inhalable solution comprising:~~

providing a propellant-free inhalable solution comprising a pharmaceutical composition according to claim 11 and a solvent comprising one of water, ethanol and a mixture of water and ethanol; and

administering a dosage of the propellant-free inhalable solution by nebulizing the inhalable solution in an inhaler.

23. (Currently Amended) ~~Use of a composition according to one of claims 1 to 19 for preparing a medicament for treating inflammatory or obstructive diseases of the respiratory tract. A method of preparing a medicament for treating inflammatory or obstructive diseases of the respiratory tract, the method comprising forming the medicament with a pharmaceutical composition according to claim 1.~~

24. (New) The pharmaceutical composition of claim 1, further comprising a pharmaceutically acceptable excipient.

25. (New) The pharmaceutical composition according to claim 1, wherein the weight ratio of the at least one anticholinergic to the at least one inhibitor of TNF alpha synthesis or action is in the range from 1:250 to 1:2.

26. (New) The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is provided in a single administration amount including a combination of the at least one anticholinergic and the at least one inhibitor of TNF alpha synthesis or action in an amount of 10 µg to 5000 µg.

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27. (New) The inhalable powder according to claim 12, wherein the at least one excipient has a maximum average particle size between 10  $\mu\text{m}$  and 150  $\mu\text{m}$ .

28. (New) The pharmaceutical composition according to claim 19, wherein the pH of the inhalable solution or suspension ranges from 2-5.